APR 0 3 2014

K132447

510(K) SUMMARY

This summary of 510(k)-safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Submitter:	Vital Connect Inc. 900 East Hamilton Avenue Suite 500 Campbell, CA 95008
Contact Person:	Sam Mostafavi Vice President of Quality Assurance and Regulatory Affairs E-mail: smostafavi@vitalconnect.com Phone: (408) 963-4620 Fax: (408) 963-2828 Vital Connect Inc. 900 East Hamilton Avenue Suite 500 Campbell, CA 95008
Date Prepared:	March 27, 2014
Trade name:	VitalConnect Platform (consisting of VitalConnect Sensor, Relay Software Library and Secure Server Software Library)
Classification:	Class II
Classification:	21 CFR 870.2910, Product Code: DRG • Transmitters and Receivers, Physiological Signal, Radiofrequency 21 CFR 870.1025, Product Code: DSI • Arrhythmia detection and alarm (including ST-segment measurement and alarm)
Predicate Device:	• CareFusion, Wireless Monitoring System, 510(k) #: K110809 • Preventice, BodyGuardian System, 510(k) #: K121197 • Corventis, Mobile Patient Management System, 510(k) #: K083287
Classification Panel:	Cardiology
Device Description:	The VitalConnect Platform is a wireless data collection system that monitors physiological data and consists of the following sub systems: • VitalConnect Sensor (includes adhesive Patch and Sensor Module) • Relay Software Library • Server Software Library

	VitalConnect Platform sub-system includes: • **VitalConnect Sensor** a) Patch The Patch is designed as a disposable self-adhesive interface to the body. b) Sensor Module Residing within the patch, the sensor module performs processing functions related to capture of physiological data and also performs bi-directional communication with the relay device. • **VitalConnect Relay Software Library** The Relay Software Library manages bi-directional communication between the Sensor Module and the Server Software Library and is installed on a relay device. • **VitalConnect Secure Server Software Library** The Server Software Library is installed on a central server, manages the upload, processing and storage of sensor data, as well as real-time configuration of and notifications from the VitalConnect Platform. The VitalConnect Sensor continuously gathers physiological data from the person being monitored and then transmits encrypted data via a bi-directional relay to the central server. The VitalConnect Sensor is a battery-operated adhesive patch with integrated sensors and wireless transceiver module, worn on the torso to record heart rate, electrocardiography (ECG), heart rate variability, respiratory rate, skin temperature, activity (including step count), and posture (body position relative to gravity including fall) for in-patient use.
Physical Description:	VitalConnect Sensor consisting of Patch and the Sensor Module dimensions are: • Patch: approximately 111 mm long x 47mm wide x 6 mm high (without the release liner) • Sensor Module: approximately 21 mm long x 12 mm wide x 4 mm high
Intended Use:	• The VitalConnect Platform is a wireless monitoring system intended for use by healthcare professionals for unattended surveillance of physiological data within healthcare settings. This includes heart rate, electrocardiography (ECG), heart rate variability, respiratory rate, skin temperature, activity (including step count), and posture (body position relative to gravity including fall). Data is transmitted wirelessly to a central location where it is stored for analysis. The VitalConnect Platform can be configured by Authorized Persons to notify healthcare professionals when

	physiological data falls outside selected parameters. • The device is not intended to be used on critical care patients and is intended to supplement vital signs monitoring by healthcare professionals, not to replace current standards of care. The device is intended for use on general care patients and on patients who are 18 years of age or older. It is not intended for home use.
Comparison of Technological Characteristics:	VitalConnect Platform and the primary predicate device (CareFusion, Wireless Monitoring System, 510(k) #: K110809) contain small ambulatory monitoring sensors that measure ECG, heart rate variability, respiratory rate, skin temperature, activity (including step count), and posture (body position relative to gravity including fall). All transmit their data to an external device, which in turn, transmits the data to a remote computer server that allows healthcare professionals to access and review the data. There are no fundamental differences between their technological characteristics. Additionally, we claim Preventice BodyGuardian System, K121197, and Corventis, Mobile Patient Management System, K083287 as secondary predicates. Preventice BodyGuardian System for ECG data, and Corventis, Mobile Patient Management System for Activity and Posture.
Non-Clinical Testing:	The following bench testing was conducted on the VitalConnect Platform system: • Electrocardiograph (ECG) • Heart rate • Heart rate variability • Respiration rate • Body impedance • activity (including step count), • Posture (body position relative to gravity including fall) • Bluetooth verification • Notification • Measurement accuracy • Communication, data transmission and storage • Reliability • Electromagnetic compatibility • Electrical safety testing • Co-existence testing • Software verification and validation testing • Biocompatibility verification and testing
Clinical Testing:	Clinical study was performed on human subjects.
Conclusion:	The results of the non-clinical and clinical studies demonstrate that the VitalConnect Platform is safe and effective for its intended use.

	Based on the intended use and product performance results, the subject device has been shown to be substantially equivalent to the currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 2, 2014

VITAL CONNECT, Inc.
Sam Mostafavi
VP of QA & RA
900 E. Hamilton Ave. Ste # 500
Campbell, CA 95008 US

Re: K132447
Trade/Device Name: Vitalconnect platform by VITAL CONNECT Inc.
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia detector and alarm (includes ST-segment measurement,alarm)
Regulatory Class: Class II
Product Code: DSI, DRG
Dated: February 12, 2014
Received: February 20, 2014

Dear Sam Mostafavi:

This letter corrects our substantially equivalent letter of April 3, 2014.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

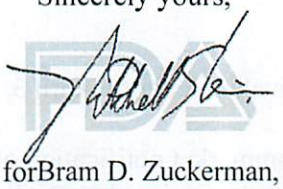
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply

with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address:
http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.
Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to:
http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address
http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



forBram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K132447

Device Name: VitalConnect Platform

Indication for use:

- The VitalConnect Platform is a wireless monitoring system intended for use by healthcare professionals for unattended surveillance of physiological data within healthcare settings. This includes heart rate, electrocardiography (ECG), heart rate variability, respiratory rate, skin temperature, activity (including step count), and posture (body position relative to gravity including fall). Data is transmitted wirelessly to a central location where it is stored for analysis. The VitalConnect Platform can be configured by Authorized Persons to notify healthcare professionals when physiological data falls outside selected parameters.
- The device is not intended to be used on critical care patients and is intended to supplement vital signs monitoring by healthcare professionals, not to replace current standards of care. The device is intended for use on general care patients and on patients who are 18 years of age or older. It is not intended for home use.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kenneth J. Cavanaugh -S